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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Dr. Heinz Welti AG, Fabrikation chemisch-pharmazeutischer Produkte, Wiesenstrasse 21, 5412 Gebenstorf,** Authorisation No. 511297-102706495 with its site **Dr. Heinz Welti AG, Fabrikation chemisch-pharmazeutischer Produkte, Wiesenstrasse 21, 5412 Gebenstorf, Switzerland,** Site No. 1002243 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland;

that from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **19.08.2022** (dd.mm.yyyy) , it is considered that it complies with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland.

That this certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

No.	*Operation*	*Scope**
1	**MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)**	
1.2	**Non-sterile products**	
1.2.1	Non-sterile products (processing operations for the following dosage forms)	
1.2.1.1	Capsules, hard shell	H/V
1.2.1.5	Liquids for external use	H/V
1.2.1.6	Liquids for internal use	H/V
1.2.1.8	Other solid dosage forms	H/V
1.2.1.11	Semi-solids	H/V
1.2.1.12	Suppositories	H/V
1.2.1.13	Tablets	H/V
1.2.2	Batch certification (technical release)	H/V
1.4	**Other products or manufacturing activity**	
1.4.1	Manufacture of:	
1.4.1.1	Herbal products	H/V
1.4.1.2	Homoeopathic products	H/V

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

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No.	Operation	Scope*
1.5	**Packaging**	
1.5.1	Primary packaging	
1.5.1.1	Capsules, hard shell	H/V
1.5.1.5	Liquids for external use	H/V
1.5.1.6	Liquids for internal use	H/V
1.5.1.8	Other solid dosage forms	H/V
1.5.1.11	Semi-solids	H/V
1.5.1.12	Suppositories	H/V
1.5.1.13	Tablets	H/V
1.5.2	Secondary packaging	H/V
1.6	**Quality control testing**	
1.6.2	Microbiological: non-sterility	H/V
1.6.3	Chemical/Physical	H/V

* Scope of authorisation:

H/V	Human and veterinary medicinal products, without investigational products
V	Veterinary medicinal products only, without investigational products
I	Human investigational medicinal products
–	Not specified

Berne, **23.06.2023** (dd.mm.yyyy)
No. GMP-CH-1004509

Swissmedic, Swiss Agency for Therapeutic Products

M. Baumann

Marianne Baumann

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